- (e) Calibration and daily performance check samples; milkfat contents. 1. The provider of a
- 2 calibration sample under par. (b) or a daily performance check sample under par. (c) shall
- determine the known percentage content of milkfat in that sample by averaging the results of 3
- 4 milkfat tests using a method specified under subd. 4. The percentage milkfat results from those 3
- 5 milkfat tests shall not vary by more than 0.034 percentage points.
- 2. The known milkfat content of a calibration sample, expressed as a percentage of the
- sample weight, shall be at least 2.5%. Within a set of calibration samples, the difference in
- 8 known milkfat content between the lowest milkfat sample and the highest milkfat sample,
- 9 expressed as a percentage of average sample weight, shall be at least 2.5%.
- 3. The known milkfat content of a daily performance check sample, expressed as a
- percentage of the sample weight, shall be at least 2.8%. Within a set of daily performance check
- samples, the difference in known milkfat content between the lowest milkfat sample and the
- highest milkfat sample, expressed as a percentage of average sample weight, shall be at least
- 14 1.5%.
- 4. To determine the milkfat content of a calibration sample or daily performance check
- sample, the sample provider shall use either a manual or robotic version of the Modified
- 17 Mojonnier method as described in the "Official Methods of Analysis of AOAC International,"
- 18 18th edition (2005), section 989.05.
- Note: The "Official Methods of Analysis of AOAC International," 18th edition (2005), is on file with the
- division and the legislative reference bureau, and may be obtained from AOAC International, 2275 Research Blvd.,
- 21 Rockville, MD 20850, website http://www.aoac.org.
- 23 (f) Calibration and daily performance check samples; protein contents. 1. The provider of a
- calibration sample under par. (b) or a daily performance check sample under par. (c) shall
- 25 determine the known percentage content of protein in that sample by averaging the results of 3

- protein tests using the method specified under subd. 3. The percentage protein results from those
- 2 3 tests shall not vary by more than 0.034 percentage points.
- 2. The known protein content of a calibration or daily performance check sample, expressed
- 4 as a percentage of sample weight, shall be at least 2.7%. Within a set of calibration samples, the
- 5 difference in known protein content between the lowest protein sample and the highest protein
- 6 sample, expressed as a percentage of average sample weight, shall be at least 0.7%. Within a set
- of daily performance check samples, the difference in known protein content between the lowest
- 8 protein sample and the highest protein sample, expressed as a percentage of average sample
- 9 weight, shall be at least 0.5%.
- 3. To determine the protein content of a calibration sample or daily performance check
- sample, the sample provider shall use the traditional or block digester/steam distillation Kjeldahl
- method as described in the "Official Methods of Analysis of AOAC International," 18th edition
- 13 (2005), section 991.20.

Note: The "Official Methods of Analysis of AOAC International," 18th edition (2005), is on file with the division and the legislative reference bureau, and may be obtained from AOAC International, 2275 Research Blvd., Rockville, MD 20850, website http://www.aoac.org.

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- (g) Calibration and daily performance check samples; total solids. 1. The provider of a
- calibration sample under par. (b) or a daily performance check sample under par. (c) shall
- 20 determine the known percentage content of total solids in that sample by averaging the results of
- 3 total solids tests using the method specified under subd. 3. The percentage total solids results
- from those 3 tests shall not vary by more than 0.054 percentage points.
- 23 2. The known total solids content of a calibration or daily performance check sample,
- expressed as a percentage of sample weight, shall be at least 11%. Within a set of calibration
- samples, the difference in known total solids content between the lowest total solids sample and
- the highest total solids sample, expressed as a percentage of average sample weight, shall be at

- least 2.00%. Within a set of daily performance check samples, the difference in known total
- 2 solids content between the lowest total solids sample and the highest total solids sample,
- 3 expressed as a percentage of average sample weight, shall be at least 1.5%.
- 4 3. To determine the total solids content of a calibration sample or daily performance check
- sample, the sample provider shall use the direct forced air oven drying method as described in
- 6 the "Official Methods of Analysis of AOAC International," 18th edition (2005), section 990.20.

Note: The "Official Methods of Analysis of AOAC International," 18th edition (2005), is on file with the division and the legislative reference bureau, and may be obtained from AOAC International, 2275 Research Blvd., Rockville, MD 20850, website http://www.aoac.org.

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- (h) Calibration and daily performance check samples; solids-not-fat. The provider of a
- calibration sample under par. b or a daily performance check sample under par (c) shall calculate
- the known percentage content of solids-not-fat in that sample by subtracting the percent milkfat
- as determined under par. (e) from the total solids for that sample as determined under par. (g).
- 15 The calculation method shall be that described in the "Official Methods of Analysis of AOAC
- International," 18th edition (2005), section 990.21.

Note: The "Official Methods of Analysis of AOAC International," 18th edition (2005), is on file with the division and the legislative reference bureau, and may be obtained from AOAC International, 2275 Research Blvd., Rockville, MD 20850, website http://www.aoac.org.

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- 21 (i) Automated testing devices; constant voltage. A constant voltage regulator shall be 22 connected to, or form a part of, every milk component testing device that is in line with a single
- phase 115 or 220-volt power supply.
- 24 (j) Records related to calibrations, daily performance checks, and reference checks. 1. A
- dairy plant operator shall keep a record of every calibration, performance check, or reference
- 26 check conducted on a milk component testing device under this section.

2. Every record required under subd. 1 shall be signed by the licensed tester who made the record. Calibration records shall be kept separate from performance check and reference check records.

(k) Accuracy of devices; division audit. The division may audit the accuracy of milk component testing devices using test samples prepared by the division under pars. (e) to (h).

SUBCHAPTER VI

INSPECTION AND ENFORCEMENT

ATCP 65.910 Inspection of dairy farms; general. (1) INSPECTION BY DAIRY PLANT OPERATOR. Before a dairy plant operator, including a milk contractor that submits a milk producer license application on behalf of a milk producer and thereby certifies that the milk producer's dairy farm and milking operations comply with applicable requirements under this chapter, submits a milk producer license application or a grade A permit application under s. ATCP 65.02 on behalf of a milk producer, the dairy plant operator shall inspect the dairy farm for compliance with the dairy farm standards under subch. II. The dairy plant operator, when submitting the producer's license or permit application, shall include a copy of the dairy plant operator's inspection report and shall certify that the dairy farm facilities comply with dairy farm standards under subch. II. The department may, at other times, require a dairy plant operator to inspect a dairy farm as necessary.

(2) INSPECTION BY THE DIVISION. The division shall inspect dairy farms for compliance with dairy farm standards under subch. II. The division shall inspect a grade A dairy farm at the frequency given in s. ATCP 65.912 and a grade B dairy farm at least once every year. For the purpose of conducting a lawful inspection under this chapter, the department may exercise its authority under ss. 93.08, 93.15 (2), and 97.12 (1), Stats.

- 1 (3) VARIANCES. The division administrator, or the division administrator's designee, may
- 2 issue a written waiver granting a variance from a dairy farm standard under subch. II if the
- division determines that the variance is reasonable and necessary under the circumstances, it will
- 4 not compromise the purpose served by the standard, and the milk producer does not hold a grade
- 5 A farm permit.
- 6 ATCP 65.912 Performance-based grade A dairy farm inspections. (1) GENERAL. The
- 7 division shall use the performance standards in this section to determine grade A dairy farm
- 8 inspection frequency. The division shall evaluate each grade A dairy farm every 3 months, on
- 9 the basis of information including inspection reports, milk quality tests, and department
- compliance actions taken during the preceding 12 months. As provided in subs. (2) to (5), the
- division shall place each dairy farm in one of the following categories:
- 12 (a) Twelve-month inspection interval.
- (b) Six-month inspection interval.
- (c) Four-month inspection interval.
- 15 (d) Three-month inspection interval.
- 16 (2) TWELVE-MONTH INSPECTION INTERVAL. The division shall inspect a grade A dairy farm
- in the twelve-month inspection interval category at least once every 12 months. The division
- shall place a dairy farm in this category if all the following apply, based on dairy farm inspection
- reports, milk quality tests, and department compliance actions, during the preceding 12 months:
- 20 (a) None of the milk producer's reported standard plate count (SPC) results exceed 25,000
- per ml., except that one reported SPC result may exceed 25,000 per ml. if it is not more than
- 22 100,000 per ml.

- 1 (b) None of the milk producer's reported somatic cell count (SCC) results exceed 500,000
- 2 per ml.
- 3 (c) None of the milk shipped by the milk producer has been found to contain a drug residue,
- 4 and the department has not issued any warning to the milk producer under s. ATCP 65.922 (1) or
- 5 65.920 (5) (c).
- 6 (d) No dairy farm inspection report shows more than 5 violations, a violation observed
- during consecutive inspections, a violation that creates a substantial risk of adulteration, or a
- 8 violation that creates an imminent health hazard.
- 9 (e) The department has not suspended the producer's grade A dairy farm permit or milk
- 10 producer license.
- (f) The producer's latest water supply test does not show any violation of s. ATCP 65.10.
- (g) The milk producer has not violated any milk temperature or cooling standards under this
- 13 chapter.
- 14 (3) SIX-MONTH INSPECTION INTERVAL. The division shall inspect a grade A dairy farm in the
- six-month inspection interval category at least once every 6 months. The division shall place a
- dairy farm in this category if all the following apply, based on dairy farm inspection reports, milk
- quality tests, and department compliance actions, during the preceding 12 months:
- (a) The dairy farm fails to qualify under sub. (2).
- 19 (b) The department has issued no more than one warning to the milk producer under s. ATCP
- 20 65.920 (5) (a) (1) to (3).
- (c) None of the milk shipped by the milk producer has been found to contain a drug residue,
- and the department has not issued any warning to the milk producer under ss, ATCP 65.922(1) or
- 23 65.920(5) (c).

- 1 (d) No dairy farm inspection report shows more than 5 violations, a violation observed
- during consecutive inspections, a violation that creates a substantial risk of adulteration, or a
- 3 violation that creates an imminent health hazard.
- 4 (e) The department has not suspended the producer's grade A dairy farm permit or milk
- 5 producer license.
- 6 (f) The producer's latest water supply test does not show any violation of s. ATCP 65.10.
- 7 (g) The milk producer has not violated any milk temperature or cooling standards under this
- 8 chapter.
- 9 (4) FOUR-MONTH INSPECTION INTERVAL. (a) The division shall inspect a grade A dairy farm
- in the four-month inspection interval category at least once every 4 months. The division shall
- place a dairy farm in this category if subs. (2), (3) and (5) do not apply and if any of the
- following apply based on dairy farm inspection reports, milk quality tests, and department
- compliance actions, during the preceding 12 months:
- 1. At least one load of milk shipped by the milk producer has been found to contain a drug
- 15 residue.
- 2. At least one violation for improper milk cooling under s. ATCP 65.18 (4), drug use and
- storage under ss. ATCP 65.20 (5) and 65.22 (8), or cleaning and sanitization of utensils and
- equipment under s. ATCP 65.12 was noted during the most recent inspection.
- 19 (b) Once the division places a dairy farm in the four-month inspection interval category, the
- 20 division may not reassign the dairy farm to any inspection category under sub. (2) or (3) until a
- date that is at least 12 months after the division's next 3-month evaluation of the dairy farm under
- 22 this section.

- 1 (5) THREE-MONTH INSPECTION INTERVAL. (a) The division shall inspect a grade A dairy farm
- 2 in the three-month inspection interval category at least once every 3 months. The division shall
- 3 place a dairy farm in this category if subs. (2) to (4) do not apply and if any of the following
- 4 apply based on dairy farm inspection reports, milk quality tests, or department compliance
- 5 actions, during the preceding 12 months:
- 1. The department issued more than one warning to the milk producer under s. ATCP 65.920
- 7 (5).
- 2. The department issued more than one warning to the milk producer under s. ATCP 65.922
- 9 (1).
- 3. The division conducted more than one reinspection of the dairy farm.
- 4. The department suspended the milk producer's license or grade A dairy farm permit.
- 12 (b) Once the division places a dairy farm in the 3-month inspection interval category under
- par. (a), the division may not reassign the dairy farm to any inspection category under subs. (2)
- to (4) until a date that is at least 12 months after the division's next 3-month evaluation of the
- 15 dairy farm under this section.
- ATCP 65.920 Suspension or revocation of grade A producer permit or milk producer
- 17 license. (1) GENERAL. The department may suspend or revoke a milk producer's license, as
- provided in s. 93.06 (7), Stats. The suspension or revocation of a milk producer's license also
- suspends or revokes a grade A producer permit held by the milk producer. A dairy plant shall
- 20 not receive milk from a milk producer whose milk producer's license is suspended or revoked.
- 21 (2) ORDER FOR SUSPENSION OR REVOCATION. Except when a summary suspension is ordered
- as provided under sub. (3), the department may not suspend or revoke a milk producer's license
- except by order of the secretary or the secretary's designee, as provided in ch. ATCP 1, after

- notice and opportunity for hearing under subch. III of ch. 227, Stats. The division may file a
- 2 written complaint with the department, seeking the suspension or revocation of a milk producer's
- 3 license. Pending completion of the suspension or revocation, the secretary or secretary's
- 4 designee may issue interim orders as necessary to protect the public health, safety, and welfare.
- 5 (3) SUMMARY SUSPENSION BY THE DIVISION. The division may issue a written notice
- 6 summarily suspending a milk producer's license if the division makes a written finding in its
- 7 suspension notice that the milk producer has refused to permit inspection or sampling authorized
- by law, or that one or more conditions in pars. (a) to (e) are present, or one or more conditions
- 9 indicate the sale or shipment of milk from the milk producer's dairy farm poses an imminent
- hazard to public health and there is a reasonable likelihood that the hazard will continue if the
- milk producer's license is not summarily suspended. A summary suspension notice shall comply
- with s. ATCP 65.925 and becomes effective when served on the milk producer. A milk producer
- served a summary suspension may request a hearing on the summary suspension notice, as
- provided in s. ATCP 65.928.
- 15 (a) An inspection of the milk producer's dairy farm reveals gross violations of dairy farm
- standards under subchapter II, or reveals violations that constitute an acute hazard to public
- 17 health.
- 18 (b) A confirmed standard plate count or plate loop count on the milk producer's milk exceeds
- 19 1,000,000 per ml.
- 20 (c) Milk from the milk producer's dairy farm is reasonably believed to contain pesticides or
- 21 toxic substances that may be harmful to humans.
- 22 (d) An infectious disease, transmissible to humans through milk, is diagnosed by a licensed
- veterinarian in the milk producer's herd.

- (e) The producer has not made an agreement with the division for the disposition of
- violations, as required in any warning notice issued under s. ATCP 65.922 (4) or (5).
- 3 (4) INSPECTION BEFORE REINSTATEMENT; REINSPECTION FEE. If an inspection is required for
- 4 reinstatement of a grade A producer permit or milk producer license that is suspended or revoked
- 5 under this section, the department shall charge a reinspection fee under s. ATCP 65.02 (19) for
- 6 the inspection.
- 7 (5) WARNING NOTICE PRECEDING A SUSPENSION OF A GRADE A MILK PRODUCER PERMIT. (a)
- 8 The division shall mail, serve in person, or prominently post in the milkhouse a written warning
- 9 to a milk producer holding a Grade A milk producer permit whenever any of the following
- 10 occurs:
- 1. Two of the last 4 bacterial counts reported to the division under s. ATCP 65.70 (2) (d)
- exceed 100,000 per ml., in violation of the standard for grade A milk under s. ATCP 65.70 (2).
- 2. Two of the last 4 somatic cell counts reported to the division under s. ATCP 65.70 (4) (e)
- exceed 750,000 per ml., for cow or sheep milk, or 1,000,000 per ml. for goat milk, in violation of
- the standard under s. ATCP 65.70 (4).
- 3. Two of the last 4 milk temperature readings violate standards for grade A milk under s.
- 17 ATCP 65.70 (5).
- 4. A division representative finds a key violation as defined in s. ATCP 65.01 (33) during an
- inspection, including one or more repeat violations during 2 consecutive inspections, on a grade
- 20 A dairy farm.
- (b) A warning notice, under par. (a) 1. to 3, shall state that the milk producer's grade A
- 22 producer permit will be suspended if milk quality testing indicates a subsequent violation of the
- standard under s. ATCP 65.70 to which the warning notice pertains. A copy of the notice shall

- be mailed to the dairy plant operator who receives the milk producer's milk. A warning notice
- becomes effective 3 business days after it is mailed, and remains in effect as long as the standard
- cited in the warning notice is violated on 2 of the last 4 reported tests.
- 4 (c) A warning notice, under par. (a) 4, shall state that the department will suspend the milk
- 5 producer's grade A producer permit if the producer does not correct the violation by a deadline
- date specified in the notice. The division representative shall specify a correction deadline based
- 7 on the seriousness of the key violation and the time reasonably required to correct the key
- violation. The correction deadline shall be not less than 3 days nor more than 65 days after the
- 9 division representative issues the warning notice. The division representative shall mail or
- deliver a copy of the warning notice to the dairy plant operator or milk contractor who procures
- milk from the milk producer. The warning notice shall include a notice of the milk producer's
- right to hearing under s. ATCP 65.928.
- (d) Not less than 3 calendar days nor more than 21 calendar days after a warning notice under
- par. (a) 1. to 3. becomes effective, the dairy plant operator, who receives the milk from the
- warned milk producer, shall obtain and test a sample of the milk producer's milk for compliance
- with the milk quality standard cited under par. (a) 1. to 3. A milk sample collected under s.
- 17 ATCP 65.38 and tested by a dairy plant operator under subchapter V satisfies this requirement,
- provided that the sample is obtained and tested within the time period specified under this
- 19 paragraph, and the dairy plant operator reports the test result to the division within the applicable
- 20 reporting time specified under subch. V.
- 21 (6) SUSPENSION OF A GRADE A MILK PRODUCER PERMIT. (a) The division shall mail a written
- 22 notice to a milk producer suspending the milk producer's grade A producer permit, if any of the
- 23 following occurs while a warning notice under s. ATCP 65.920 (5) remains in effect:

- 1. Three of the last 5 bacterial counts reported to the division under ss. ATCP 65.70 (2) (d)
- and 65.920 (5) (c) exceed 100,000 per ml.
- 2. Three of the last 5 somatic cell counts reported to the division under ss. ATCP 65.70 (4)
- 4 (e) and 65.920 (5) (c) exceed 750,000 per ml.
- 5 3. Three of the last 5 milk temperature readings violate standards for grade A milk under s.
- 6 ATCP 65.70 (5).
- 4. If within 7 days after the correction deadline under subd. (5) (a) 4. the division
- 8 representative finds that the milk producer has not corrected a key violation cited in the warning
- 9 notice issued under par. (5) (a) 4.
- 10 (b) The suspension of a milk producer's grade A producer permit becomes effective when the
- suspension notice is served under s. ATCP 65.925 (6). The department shall give prior oral or
- written notice of the suspension, and mail or deliver a copy of the suspension notice, to the dairy
- plant operator who receives the milk producer's milk. The suspension notice shall comply with
- s. ATCP 65.925. If a suspension notice is served under par. (a) 4., the division representative
- shall, within 24 hours, notify the dairy plant operator who receives the milk producer's milk, and
- place a tag indicating that the milk is now to be handled as grade B milk on the outlet valve of
- the bulk tank or the outlet valve of a bulk milk tanker into which milk is directly transferred by a
- milking system under s. ATCP 65.16 (5), in order to notify the bulk milk weigher and sampler of
- the suspension. A person adversely affected by the suspension notice may request a hearing on
- the notice as provided under s. ATCP 65.928.
- 21 (7) REINSTATEMENT OF GRADE A MILK PRODUCER PERMIT. (a) A milk producer may ask the
- department to reinstate a grade A producer permit suspended under s. ATCP 65.920 (6). The
- 23 milk producer shall make the request in writing, on a form provided by the department under s.

- ATCP 65.925(4). If the suspension occurred because of a violation of sub. (6) (a) 1. to 3., the
- 2 request shall include the result of a milk quality test performed by the dairy plant operator who
- receives the milk producer's milk on a milk sample collected after the effective date of the
- 4 suspension, showing that the milk producer is no longer violating the relevant milk quality
- 5 standard.
- 6 (b) Within 7 days after the department receives a complete reinstatement request that
- 7 complies with par. (a) the department shall do one of the following:
- 1. If the milk producer seeks reinstatement of a grade A producer permit suspended under
- 9 sub. (6) (a) 1. to 3., the department shall reinstate the grade A producer permit. The department
- shall notify the milk producer and the dairy plant operator who receives the milk producer's milk
- of the reinstatement within 24 hours.
- 2. If the milk producer seeks reinstatement of a grade A producer permit suspended under
- sub. (6) (a) 4., the department shall inspect the dairy farm and charge a reinspection fee under s.
- 14 ATCP 65.02 (19). A division representative shall reinstate the grade A producer permit if the
- division representative finds that the milk producer has corrected all the conditions potentially
- 16 responsible for the violations cited in the suspension notice. The division representative shall
- 17 notify the dairy plant operator who receives the milk producer's milk of the reinstatement within
- 18 24 hours.
- (c) If a milk producer does not request reinstatement, under par. (a), within 6 months after
- 20 the producer's grade A producer permit is suspended under this section, the permit is
- automatically revoked at the end of the 6-month period. Once revoked, the grade A producer
- permit may not be reinstated except upon the filing of a new application under s. ATCP 65.02
- 23 (10). Written notice of the reinstatement process shall be provided to the milk producer at the

- time of suspension. This paragraph does not apply if the suspension of the milk producer's grade
- 2 A producer permit has been contested, and the contested case proceedings are still pending. The
- time limit for the reinstatement request is measured from the conclusion of the contested case
- 4 proceedings concerning the suspension of the milk producer's grade A producer permit.

Note: Subsection (7) does not prohibit the division from summarily suspending a milk producer's license and grade A producer permit under s. ATCP 65.920 without prior warning if the division determines that any of the circumstances identified under s. ATCP 65.920 (3) exist.

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- ATCP 65.922 Enforcement actions taken in response to drug residue violations. (1)
- WARNING NOTICE. Whenever the division receives notice under s. ATCP 65.72 (9) that a milk
- producer milk sample has yielded a confirmed positive test result for drug residue, the division
- shall mail a warning notice to that milk producer. The warning notice takes effect 3 business
- 13 days after it is mailed.
- 14 The warning notice shall include all of the following:
- 15 (a) A description of the positive drug residue findings that caused the division to issue the
- 16 notice.
- (b) The deadlines and penalties specified in subs. (2), (4), or (5).
- (c) Notice of the milk producer's right to hearing under sub. (6).
- (d) Notice that a division representative will conduct an investigation under sub. (3).
- 20 (2) DEADLINES AND PENALTIES AFTER A FIRST VIOLATION IN 12 MONTHS. (a) Grade A
- 21 producer permit suspension; 21-day deadline. The warning notice under par. (a) shall state that,
- 22 no less than 21 days after the effective date of the warning notice, the department will suspend
- 23 the milk producer's grade A producer permit unless, prior to that date, the milk producer certifies
- to the division that the milk producer has implemented a drug residue prevention program on the
- 25 milk producer's dairy farm in consultation with a licensed veterinarian.

- (b) Notice suspending grade A producer permit. If the division does not receive a milk
- 2 producer certification within the 21-day period specified under sub. (2) (a), the department shall
- mail a notice to the milk producer suspending the milk producer's grade A producer permit. The
- 4 suspension notice shall comply with s. ATCP 65.925. The suspension notice takes effect when
- 5 the suspension notice is served under s. ATCP 65.925 (6). The division shall notify the dairy
- 6 plant operator or milk contractor who procures milk from the milk producer of the suspension,
- and shall provide that dairy plant operator or milk contractor with a copy of the suspension
- 8 notice.
- 9 (c) Grade A producer permit reinstatement. If the department suspends a milk producer's
- grade A producer permit, under par. (a), the milk producer may request the department to
- reinstate the permit. Written notice of the reinstatement process shall be included in the
- suspension notice under par. (a), and shall also be provided to the milk producer at the time of
- 13 suspension.
- 1. The milk producer shall file the reinstatement request in writing, on a form provided by
- the department, under s. ATCP 65.925(4). The request shall include a certification or attestation
- that the milk producer has implemented a drug residue prevention program on the milk
- producer's dairy farm in consultation with a licensed veterinarian.
- 2. Within 7 business days after the department receives a complete reinstatement request
- under subd. 1., the division shall inspect the milk producer's dairy farm. The department shall
- 20 charge a reinspection fee for the inspection, pursuant to s. ATCP 65.02 (19). If, upon inspection,
- 21 it appears that all conditions potentially responsible for the positive drug residue finding have
- been corrected and the milk producer has implemented a qualified drug residue prevention
- 23 program in consultation with a licensed veterinarian, the division representative shall reinstate

the milk producer's grade A producer permit and shall notify the dairy plant operator or milk

2 contractor of the reinstatement within 24 hours.

3. If a milk producer does not request reinstatement under subd. 1., within 6 months after the

4 milk producer's grade A producer permit is suspended under par. (a), the permit is revoked

5 automatically at the end of the 6-month period. A permit, once revoked, may not be reinstated

unless the milk producer files a new application under s. ATCP 65.02 (11). This subdivision

does not apply if the milk producer contests the grade A producer permit suspension and the

contested case proceeding is pending. The time limit for the reinstatement request is measured

from the conclusion of the contested case proceedings concerning the suspension of the milk

producer's grade A producer permit.

(d) Milk producer license suspension; 45-day deadline. The warning notice under par. (a) shall state that, no less than 45 days after the effective date of the warning notice, the department will initiate action to suspend the milk producer's license unless, prior to that date, the milk producer certifies to the division that the milk producer has implemented a drug residue prevention program on the milk producer's dairy farm in consultation with a licensed

veterinarian.

17 (e) Milk producer license suspension; failure to implement drug residue prevention program.

18 If the division does not receive a milk producer certification within the 45-day period specified

under par. (d), the division shall file a complaint asking the department to suspend the milk

producer's license until the milk producer implements a drug residue prevention program.

Note: The drug residue prevention program under this section should conform to the "Milk and Dairy Beef Quality Assurance Program" published by Agri-Education, Inc. A copy of that manual is on file with the division and the legislative reference bureau and may be obtained from the Milk & Dairy Beef Quality Assurance Center,

801 Shakespeare Avenue, Stratford, Iowa, 50249, telephone 800-553-2479, website

www.dgacenter.org/catalog.htm.

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- 1 (3) INVESTIGATION. After the division issues a warning notice under sub. (1), the division
- 2 representative shall conduct an investigation to determine the cause of the drug residue violation
- and to identify milk producer actions that may be necessary to prevent future violations. The
- 4 division may direct the dairy plant operator or milk contractor who procures milk from the milk
- 5 producer to conduct the investigation as the division's agent and report its findings to the
- 6 division, in writing.
- 7 (4) DEADLINE AND PENALTIES AFTER A SECOND VIOLATION WITHIN 12 MONTHS. If, at least 24
- 8 hours and not more than 12 months after a confirmed positive drug test result is reported to the
- 9 division, the division receives a notice under s. ATCP 65.72 (9) of another confirmed positive
- drug residue test result on a milk sample from a shipment received from the dairy farm operating
- under the same milk producer license, a warning notice under sub. (1) (a) shall be mailed to the
- milk producer. The warning notice takes effect 3 business days after it is mailed and shall
- include the information under sub. (1) (a), (c), and (d). The warning notice shall state that the
- department shall suspend the milk producer license under s. ATCP 65.920 for at least 5 days
- unless the milk producer agrees within 15 days of the warning notice taking effect to do all of the
- 16 following:
- 17 (a) Discard one shipment of milk, as defined by the department, pursuant to s. ATCP 65.72
- 18 (7), or pay a civil forfeiture for the maximum amount, under s. 97.72 (2), Stats., for one violation
- 19 of this subsection.
- 20 (b) Attend and present a certificate of completion for a drug residue prevention course
- approved by the department within 180 days of the warning notice taking effect. The certificate
- of course completion shall be signed by the milk producer, a licensed veterinarian, and the field
- representative of the dairy plant to which the milk producer's milk is shipped.

1 (5) DEA	DLINE AND PENALTIES	AFTER A THIRD	VIOLATION WITHIN	12 MONTHS.	If, at least 24
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- 2 hours after a second confirmed positive drug residue test result is reported to the division under
- sub. ATCP 65.922 (4), and not more than 12 months after a first confirmed positive drug residue 3
- 4 test result is reported to the division under sub. ATCP 65.922 (4), the division receives a notice
- under sub. ATCP 65.72 (9) of another confirmed positive drug residue test result on a milk 5
- 6 sample received from the dairy farm operating under the same milk producer license, a warning
- 7 notice under sub. (1) (a) shall be mailed to the milk producer. The warning notice takes effect 3
- 8 business days after it is mailed and shall include the information under sub. (1) (a), (c), and (d).
- 9 The warning notice shall state that the department shall suspend the milk producer's grade A
- producer permit, under s. ATCP 65.920, for at least 10 days unless the milk producer agrees 10
- 11 within 15 days of the warning notice taking effect to do all of the following:
- 12 (a) Discard two shipments of milk, as defined by the department, pursuant to s. ATCP 65.72
- (7), or pay a civil forfeiture for the maximum amount, under s. 97.72 (2), Stats., for two 13
- 14 violations of this subsection.

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- 15 (b) Develop and implement a drug residue prevention program approved by the department
- and present documentation indicating that this program has been implemented for at least 90 16
- 17 days after the warning notice taking effect.

18 Note: The drug residue prevention course shall cover proper administration of animal medications, be approved

19 by the department, and require collaboration between the milk producer and a licensed veterinarian.

(6) RIGHT TO INFORMAL HEARING. If a milk producer receiving a warning notice under this 21

section disputes the drug residue findings on which the notice is based, the milk producer may

request an informal hearing to discuss the drug residue findings. A request for hearing does not

automatically stay the warning notice. If the milk producer requests an informal hearing, the

division shall hold an informal hearing at the division's office or by telephone. The division shall

- 1 hold the informal hearing within 20 days after the division receives the request for hearing,
- 2 unless the milk producer agrees to a later hearing date. The division may withdraw a warning
- 3 notice if it appears that the notice was not justified.
- 4 ATCP 65.925 Suspension notice; requirements. Whenever the division suspends a milk
- 5 producer license under s. ATCP 65.920(3), or a grade A producer permit, under s. ATCP 65.922
- 6 (2) or 65.920 (6), the suspension notice shall comply with all of the following requirements:
- 7 (1) ISSUED BY AUTHORIZED PERSON. A suspension notice shall be issued by one of the
- 8 following:
- 9 (a) The division administrator.
- 10 (b) A person that the division administrator designates in writing, by name or position.
- (c) A division representative if the suspension notice is issued under s. ATCP 65.920 (6) (a)
- 12 4.
- (2) REASON FOR SUSPENSION. A suspension notice shall specify the reasons for which the
 suspension notice is issued.
- 15 (3) TERM OF SUSPENSION; REINSTATEMENT REQUIREMENT. A suspension notice shall indicate
- the term of the suspension or, if the suspension is for an indefinite term, the conditions that the
- milk producer must meet in order to obtain reinstatement of the milk producer license or grade A
- producer permit. Conditions for reinstatement shall be reasonably related to the reasons for
- which the license or permit is suspended. A summary license suspension notice under s. ATCP
- 20 65.920 (2) may authorize a dairy plant operator to receive milk from the suspended milk
- 21 producer directly or via a milk contractor, on a conditional basis, pending full reinstatement of
- 22 the milk producer's license, provided that the dairy plant operator or milk contractor performs
- 23 inspections or tests specified in the suspension order.

- 1 (4) REINSTATEMENT APPLICATION FORM. A notice suspending a grade A producer permit,
- 2 under s. ATCP 65.920 (6) (a), shall be accompanied by a reinstatement application form which
- may be used by the affected milk producer to apply for reinstatement of the milk producer's
- 4 grade A producer permit. The form shall include a statement, to be signed by the affected milk
- 5 producer, that all requirements for the reinstatement of the grade A producer permit have been
- 6 met to the best of the milk producer's knowledge. If a milk producer requests a hearing on a
- suspension under s. ATCP 65.928, a request for reinstatement under this subsection does not
- 8 constitute an admission or waiver by the milk producer with respect to any fact, issue or cause of
- 9 action.
- 10 (5) NOTICE OF RIGHT TO HEARING. A suspension notice shall include a notice that the milk
- producer may request a hearing on the suspension, as provided under s. ATCP 65.928.
- 12 (6) SERVICE ON MILK PRODUCER. A suspension notice shall be served on the affected milk
- producer by one of the following methods:
- 14 (a) By delivering the notice in person to the milk producer or to a competent member of the
- milk producer's household who is 14 years of age or older.
- (b) By mailing the notice to the milk producer. Service may be proved by an affidavit of
- mailing or by a return receipt signed by the milk producer. Absent proof of later delivery, a
- notice served by mail is considered served three business days after the date of mailing.
- (c) For a notice suspending a grade A producer permit, under s. ATCP 65.920 (6), by posting
- the suspension notice in a prominent location in the milk producer's milkhouse. A notice posted
- in the milkhouse under this paragraph is considered served at the time of posting.
- 22 (7) COPY PROVIDED TO DAIRY PLANT OPERATOR. A copy of every suspension notice shall be
- 23 mailed or delivered to the dairy plant operator or milk contractor who normally procures milk

- from the milk producer at least three days before the start of the suspension. Failure to mail or
- 2 deliver a copy to the dairy plant operator or milk contractor does not invalidate a suspension
- 3 notice.
- 4 ATCP 65.926 Dairy plant license and grade A permit suspension or revocation. (1)
- 5 The department may suspend or revoke a dairy plant license or grade A dairy plant permit, as
- 6 provided in s. 93.06 (7), Stats. except as provided under sub. (2), the department may not
- suspend or revoke a dairy plant license or grade A dairy plant permit except by order of the
- secretary or the secretary's designee, as provided in ch. ATCP 1, after notice and opportunity for
- 9 hearing under subch. III of ch. 227, Stats. The division may file a written complaint with the
- department seeking the suspension or revocation of a dairy plant license or grade A dairy plant
- permit. Pending completion of the proceedings, the secretary or the secretary's designee may
- issue interim orders as necessary to protect the public health, safety and welfare. If an inspection
- is required for the reinstatement of a dairy plant license or grade A dairy plant permit that is
- suspended or revoked under this section, the department shall charge a reinspection fee, under s.
- 15 ATCP 65.02 (19), for the inspection.
- 16 (2) The department may suspend or revoke a dairy plant license or grade A dairy plant
- permit, as provided under s. 93.06 (7), Stats., for cause including any of the following:
- (a) A violation of this chapter or ch. ATCP 100.
- (b) Interference with lawful inspection or sampling by the department or a certifying agency
- 20 under s. ATCP 65.930, or refusal to permit lawful inspection or sampling by the department or a
- certifying agency under s. ATCP 65.930.
- 22 (c) Refusal to permit the lawful inspection or copying of documents under s. 65.44 (2).
- 23 (d) Failure to pay fees required under s. ATCP 65.04.

Note: The procedure for suspending or revoking a dairy plant license or grade A permit is specified in ch. ATCP 1.

- (3) The suspension or revocation of a dairy plant license automatically suspends or revokes any grade A permit that the dairy plant operator holds for that dairy plant.
- Note: Violations of this chapter may also result in court prosecution under s. 97.72 or 97.73, Stats.

ATCP 65.927 Holding orders; identification and disposal of adulterated milk. (1)

- HOLDING ORDER. Whenever a division representative has reasonable cause to believe that milk or a milk product examined by the division representative is adulterated or misbranded and is dangerous to health or misleading to the injury or damage of a purchaser or consumer, the division representative may issue a temporary holding order to allow for further testing or examination of the milk or milk product, pursuant to s. 97.12 (2), Stats. A holding order shall be written and shall identify the milk or milk product that is subject to the holding order. The division may extend or terminate a holding order by written notice, as provided in s. 97.12 (2), Stats. A notice extending a holding order shall be signed by the division administrator, or a person authorized in writing by the division administrator. A holding order and every notice extending a holding order shall include a notice of the recipient's right to hearing under s. ATCP 65.928.
- (2) DISPOSAL ORDER. If analysis or examination shows that milk or a milk product is adulterated or misbranded and is dangerous to health or misleading to the injury or damage of a purchaser or consumer, the division may issue a summary disposal order under s. 97.12 (2) (c), Stats., requiring the disposal or other disposition of the milk or milk product. A disposal order may be issued by the division representative who examines the milk, or by the division administrator, or by a person whom the administrator designates in writing. Where appropriate, an order may require relabeling of misbranded milk in lieu of disposal. A holding order under

- sub. (1) is not a prerequisite to a disposal order under this subsection. A disposal order shall be
- 2 issued in writing, and shall include a notice of the recipient's right to hearing under s. ATCP
- 3 65.928.
- 4 (3) IDENTIFICATION OF ADULTERATED MILK. If milk is found to be adulterated and hazardous
- to health, a division representative may identify the milk for disposal or disposition in
- 6 compliance with a notice under sub. (2). To identify the adulterated milk, the division
- 7 representative may tag the milk container and may add a harmless food grade color to the milk to
- 8 prevent its sale or use for human food purposes.
- 9 ATCP 65.928 Right of hearing. (1) HEARING REQUEST. A person adversely affected by
- any of the following division actions may ask the department to hold a hearing on that action:
- (a) The denial of a milk producer license application or grade A producer permit application
- 12 under s. ATCP 65.02.
- (b) The summary suspension of a milk producer license, under s. ATCP 65.920 (3).
- (c) The issuance of a warning notice, under s. ATCP 65.920 (5) (a).
- (d) The suspension of a grade A producer permit, under s. ATCP 65.920 (6) (a).
- (e) The denial of a reinstatement application, under s. ATCP 65.920 (5) (d) or (7).
- (f) A holding order, disposal order, or other summary action, under s. ATCP 65.927.
- (g) The suspension or revocation of a dairy plant license or grade A permit, under s. ATCP
- 19 65.926.
- 20 (2) FORM AND TIMING OF REQUEST; EFFECT PENDING HEARINGS.
- A person requesting an informal hearing, under sub. (3), shall make that request, in writing,
- 22 within 10 days after the person receives notice of the division action. A request for hearing does
- 23 not stay the effect of any action under this chapter. The filing deadline under this subsection is

- waived if the department fails to give the milk producer timely written notice of the filing
- 2 deadline.
- 3 (3) INFORMAL HEARING. (a) Whenever the department receives a hearing request under sub.
- 4 (2), the department shall conduct an informal hearing on the contested action. The hearing shall
- be conducted by a presiding officer who is a department employee or official who was not
- 6 personally involved in the investigation or decision to take the contested action, and who has
- authority to withdraw or correct the action as necessary. The division shall conduct the informal
- 8 hearing unless the contested action was taken by the division administrator. The division shall
- 9 hold the informal hearing within 20 days after it receives the hearing request under sub. (2),
- unless the person requesting the hearing agrees to a later date. The division may hold the
- informal hearing by telephone or at the division's office.
- (b) The issue for hearing, held under par. (a), shall be limited to whether the division had
- adequate grounds for the contested action. Within 2 business days after the conclusion of the
- informal hearing, the presiding officer shall issue a brief written memorandum that summarizes
- the informal hearing, and any decision or action resulting from the informal hearing. A copy of
- the memorandum shall be provided to the person who requested the hearing. The memorandum
- shall include notice of the person's right to request a full evidentiary hearing under sub. (4).
- (4) FULL EVIDENTIARY HEARING. If a person adversely affected by a division action either
- 19 files a timely written request for hearing under sub. (2), and the matter is not resolved by an
- 20 informal hearing under sub. (3), or does not want an informal hearing, the person may request a
- full evidentiary hearing before the department, pursuant to subch. III of ch. 227, Stats., and ch.
- 22 ATCP 1. The person shall make the hearing request as specified in s. ATCP 1.06. A full

- evidentiary hearing, if any, shall be held before an administrative law judge appointed by the
- 2 secretary. A request for a full evidentiary hearing does not stay any action under this chapter.
- ATCP 65.930 Grade A dairy plants; compliance monitoring and inspection. (1) AUDIT
- 4 SURVEYS BY CERTIFYING AGENCY. (a) Requirement. The division shall perform audit surveys of
- 5 grade A dairy plants, and the dairy farms shipping milk to those dairy plants, to establish a grade
- 6 A sanitation compliance rating under this chapter. The division shall survey a grade A dairy
- 7 plant, and the farms shipping milk to that dairy plant, at all of the following times:
- 1. Within 20 business days after the department first issues a grade A dairy plant permit to
- 9 the dairy plant under s. ATCP 65.04.
- 2. At least once every 2 years after the initial survey under subd. 1.
- (b) Survey method. A survey, under par. (a), shall include an inspection of the grade A dairy
- plant, an inspection of a randomly selected statistically representative sample of dairy farms in a
- BTU shipping grade A milk to that dairy plant, and an evaluation of the division's enforcement
- methods. A survey shall be conducted in compliance with "Methods of Making Sanitation
- 15 Ratings of Milk Supplies," 2013 revision, published by the Food and Drug Administration,
- Public Health Service, United States Department of Health and Human Services.
- Note: The "Methods of Making Sanitation Ratings of Milk Supplies" is on file with the division and the legislative reference bureau. Copies may be purchased from the Milk Safety Team, HFS-626, Food
- and Drug Administration, Public Health Service, United States Department of Health and Human
- 20 Services, 5100 Paint Branch Parkway, College Park, MD 20740-3835. Also available online at
- 21 http://www.fda.gov/food/guidanceregulation/federalstatefoodprograms/ucm2007965.htm.
- 22
- 23 (c) Survey rating. Based on a survey under par. (a), the division shall assign an overall grade
- A sanitation compliance rating to the dairy plant and the dairy farms in the BTU that ship milk to
- 25 that dairy plant.

(d) Unsatisfactory survey rating; grade A permit suspension. The department may suspend or 1 revoke a dairy plant's grade A permit if the sanitation compliance rating for that dairy plant under 2 3

par. (c) falls below 80%. This subsection does not prohibit the department from suspending or

revoking a grade A dairy plant permit for any other reason. 4

Note: Procedures, related to the suspension or revocation of a grade A dairy plant permit, are set forth in ch. ATCP 1. If a compliance rating falls below 80%, the department may also decertify the dairy plant as an interstate milk shipper. Decertification may prevent the dairy plant operator from shipping grade A dairy products in interstate commerce.

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- (2) INSPECTION FREQUENCY. (a) Except as provided in par. (b), the division shall inspect every grade A processing plant at least once every 3 months, every grade A receiving station at least once every 3 months, and every grade A transfer station at least once every 6 months.
- (b) Paragraph (a) does not apply to a grade A processing plant, receiving station, or transfer station that the United States food and drug administration lists as being enrolled in the program described in PMO Appendix K.

Note: PMO Appendix K describes a voluntary "hazard analysis-critical control point (HACCP)" program for dairy plants. The HACCP program serves as a partial alternative to traditional inspection. If a dairy plant is currently enrolled in the HACCP program, as indicated by the Interstate Milk Shippers List published by the United States food and drug administration, the department is not required to inspect the dairy plant with the normal frequency required under sub. (2)(a). If an enrolled dairy plant fails to comply with HACCP program standards in PMO Appendix H, the food and drug administration may "de-list" the dairy plant from the HACCP program and the department must then inspect the dairy plant at the normal frequency required by sub. (2)(a). PMO Appendix K is on file with the division and the legislative reference bureau. Copies may be obtained from the department at cost or online at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk.

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(3) DAIRY PRODUCT SAMPLING; FREQUENCY. (a) Pasteurized milk and dairy products; sample testing. Except as provided in par. (c), the division in every consecutive 6-month period shall collect from every grade A dairy plant at least 4 samples of each pasteurized grade A dairy product produced by that dairy plant. The division shall collect each sample in a separate month, except that the division may collect 2 of the samples in the same month if it collects those 2 samples at least 20 days apart and collects the other two samples in two other months. Dairy plants producing pasteurized grade A dairy products on an intermittent basis shall notify the

division of intended			

- 2 The division shall measure and record the temperature of each pasteurized grade A dairy product
- from which the samples are collected and shall test the samples for bacteria counts, coliform
- 4 counts, and beta lactam drug residues. The division may collect additional samples and perform
- 5 additional tests that the division considers necessary.
- 6 (b) Raw milk held at dairy plant; sample testing. During every consecutive 6-month period,
- 7 the division shall collect at least 4 samples of commingled raw milk from each grade A dairy
- 8 plant that receives raw milk. The division shall collect each sample in a separate month, except
- 9 that the division may collect 2 of the samples in the same month if it collects those 2 samples at
- least 20 days apart and collects the other two samples in two other months. The division shall
- measure and record the temperature of the raw commingled milk from which the division
- collects each sample and shall test each sample for bacterial counts and beta lactam drug
- residues. The division may collect additional samples and perform additional tests that the
- 14 division considers necessary.
- (c) Paragraph (a) does not apply to a grade A condensed or dry milk product that is not
- produced on a continuous monthly basis, provided that the division collects at least 5 samples
- 17 within each continuous production period.
- 18 SECTION 3. ATCP 65 Appendix A is created to read:
- 19 Chapter ATCP 65
- 20 APPENDIX A

21 3-A SANITARY STANDARDS AND ACCEPTED PRACTICES

- The following 3-A standards and 3-A accepted practices establish criteria for the sanitary construction
- and operation of dairy handling and processing equipment. These standards are published by the "3-A
- Sanitary Standards, Inc., 1451 Dolley Madison Boulevard, Suite 210, McLean, VA 22101-3850, website
- 25 www.3-A.org, Telephone: (703) 790-0295, Fax: (703) 761-6284. Copies are on file with the department
- and the reviser of statutes. Copies may be obtained from "3-A Sanitary Standards, Inc. Online Store" at
- 27 http://www.techstreet.com.

You may also search, order and download standards (in PDF format) by visiting http://www.3-

2 A.org.

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3-A SANITARY STANDARDS

Doc. No.	Title (3-A Sanitary Standards for:)	Effective
00-00	General Requirements	10/2014
01-09	Insulated Tanks	11/2013
02-11	Centrifugal and Positive Rotary Pumps	7/2012
04-05	Homogenizers and Reciprocating Pumps	6/2012
05-15	Stainless Steel Automotive Transportation Tanks	11/2002
10-04	Filters Using Single Service Filter Media	11/2000
11-09	Plate-Type Heat Exchangers	8/2010
12-07	Tubular Heat Exchangers	11/2003
13-11	Farm Milk Cooling and Holding Tanks	7/2012
16-05	Product Evaporators and Vacuum Pans	8/1997
17-11	Formers, Fillers, and Sealers of Containers for Fluid Products	11/2012
18-03	Multiple-Use Rubber and Rubber-Like Materials	8/1999
19-07	Batch and Continuous Freezers Ice Cream, Ices, and Similarly Frozen	12/2008
	Foods	
20-27	Multiple-Use Plastic Materials	7/2011
21-01	Centrifugal Separators and Clarifiers	11/2006
22-08	Silo-Type Storage Tanks	11/2004
23-06	Equipment for Packaging Viscous Products	11/2012
24-03	Non-Coil Type Batch Pasteurizers	7/2010
25-03	Non-Coil Type Batch Processors	11/2002
26-05	Sifters for Dry Products	4/2007
27-06	Equipment for Packaging Dry Products	5/2010
28-04	Flow Meters	1/2009
29-03	Air Eliminators	8/2011
30-01	Farm Milk Storage Tanks	9/1984
31-06	Scraped Surface Heat Exchangers	9/2010
32-03	Uninsulated Tanks	3/2013
33-02	Metal Tubing	9/2009
34-02	Portable Bins for Dry Products	9/1992

Doc. No.	Title (3-A Sanitary Standards for:)	Effective
35-04	Blending Equipment	8/2011
36-01	Inline Rotor-Stator Mixers	11/2003
38-00	Cottage Cheese Vats	8/1997
39-01	Pneumatic Conveyors for Dry Products	11/2003
40-04	Bag Collectors	3/2012
41-03	Mechanical Conveyors for Dry Products	1/2008
42-01	In-Line Strainers	11/1997
44-03	Diaphragm Pumps	11/2001
45-02	Crossflow Membrane Modules	11/2003
46-03	Refractometers and Energy-Absorbing Optical Sensors	11/2002
49-01	Air Driven Sonic Horns for Dry Products	11/2001
50-01	Level Sensing Devices for Dry Products	11/2001
.51-01	Plug-Type Valves	11/1998
52-02	Plastic Plug-Type Valves	11/1998
53-06	Compression-Type Valves	5/2009
54-02	Diaphragm-Type Valves	11/1997
55-02	Boot Seal Type Valves	8/2010
56-00	Inlet and Outlet Leak-Protector Plug-Type Valves	5/1993
57-02	Disc-Type Valves	5/2008
58-01	Vacuum Breakers and Check Valves	8/2010
59-00	Automatic Positive Displacement Samplers for Fluid Products	11/1993
60-01	Rupture Discs	7/2013
61-01	Steam Injection Heaters	9/2006
62-02	Hose Assemblies	11/2010
63-03	Sanitary Fittings	11/2002
64-00	Pressure Reducing and Back Pressure Regulating Valves	11/1993
65-01	Sight and/or Light Windows and Sight Indicators in Contact with Product	6/2008
68-00	Ball-Type Valves	11/1996
70-02	Italian-Type Pasta Filata Style Cheese Cookers	7/2013
71-01	Italian-Type Pasta Filata Style Cheese Moulders	11/2002
72-01	Italian-Type Pasta Filata Style Moulded Cheese Chillers	11/2002
73-01	Shear Mixers, Mixers, and Agitators	10/2005
74-06	Sensors and Sensor Fittings and Connections Used on Equipment	8/2013

Doc. No.	Title (3-A Sanitary Standards for:)	Effective
75-01	Belt-Type Feeders	6/2012
78-01	Spray Cleaning Devices Intended to Remain in Place	11/2003
81-00	Auger-Type Feeders	11/1998
82-00	Pulsation Dampening Devices	11/2002
83-00	Enclosed Cheese Vats and Tables	11/2003
84-02	Personnel Access Ports for Wet Applications	6/2007
85-03	Double-Seat Mixproof Valves	4/2014
87-00	Mechanical Strainers	11/2007
88-00	Machine Leveling Feet and Supports	12/2006
95-00	Transportation Tank Vents	10/2012
101-00	Pipeline Product Recovery Equipment Using Projectiles	8/2012

3-A ACCEPTED PRACTICES

Doc. No.	Title (3-A Sanitary Standards Topic)	Effective
603-07	Sanitary Construction, Installation, Testing, and Operation of High- Temperature Short-Time and Higher-Heat Shorter-Time Pasteurizer Systems	11/2005
604-05	Supplying Air Under Pressure for Contact with Product or Product Contact Surfaces	11/2004
605-04	Permanently Installed Product and Solution Pipelines and Cleaning Systems	8/1994
606-05	Design, Fabrication, and Installation of Milking and Milk Handling	11/2002
	Equipment	
607-05	Spray Drying Systems	11/2004
608-02	Instantizing Systems	11/2001
609-03	Method of Producing Steam of Culinary Quality	11/2004
610-02	Sanitary Construction, Installation, and Cleaning of Crossflow Membrane Processing Systems	7/2009
611-00	Farm Milk Cooling and Storage Systems	11/1994
612-00	Plant Environmental Air Quality	12/2011

- SECTION 4. ATCP 77.01 (4m) is amended to read:
- 2 ATCP 77.01 (4m) "Drug residue screening test" means any test under s. ATCP 77.02 (1)
- 3 (f) to (1) (t) or (1) (zd), other than a confirmatory test, that a person uses to comply with drug
- 4 residue testing requirements under s. ATCP 60.19 65.72.
- 5 SECTION 5. ATCP 77.02 (1) (zd) is amended to read:
- 6 ATCP 77.02 (1) (zd) Tests performed to comply with ch. ATCP 60 or 80 65, other than
- 7 milk component tests which are not related to public health.
- 8 SECTION 6. ATCP 77.23 (1) (a) and (1) (b) 2. are amended to read:
- ATCP 77.23 (1) (a) The department may approve a laboratory to perform a drug residue
- test as a screening test, even though the laboratory is not certified under s. ATCP 77.03 to
- perform the test as a confirmatory test. An approval expires on December 31 of each year. An
- approved laboratory shall comply with s. ATCP 60.22 (1) (b) <u>65.76 (2) (b)</u>.
- ATCP 77.23 (1) (b) 2. The laboratory has written agreements with one or more certified
- laboratories to provide the confirmatory testing required under s. ATCP 60.22 (1) (b) 3 65.76 (2)
- 15 <u>(b) 3</u>.
- SECTION 7. ATCP 80 is repealed.
- SECTION 8. ATCP 81.91 (1) is amended to read:
- ATCP 81.91 (1) DESCRIPTION. Baby Swiss cheese is the food prepared by the process under
- sub. (2) or by any other process which produces a finished cheese having the same physical and
- 20 chemical properties as that produced under sub. (2). Baby Swiss cheese has round, well-formed
- 21 holes or eyes developed throughout the cheese. The minimum milkfat content of baby Swiss
- cheese is 45% by weight of the solids. The maximum moisture content is 43% by weight, as
- determined by a method that complies with s. ATCP 80.32 65.86. Baby Swiss cheese shall be

- held at the point of manufacture for 60 days prior to distribution, or be made from pasteurized
- 2 milk. If pasteurized milk is used, the phenol equivalent value of 0.25 grams of baby Swiss
- 3 cheese shall not exceed 3 micrograms.
- 4 SECTION 9. ATCP 82.04 (1) (b) is amended to read:
- 5 ATCP 82.04 (1) (b) Collect test samples of milk required under s. ATCP 60.17 65.38.
- 6 SECTION 10. ATCP 82.04 (9) (b) is amended to read:
- ATCP 82.04 (9) (b) Collect test samples of grade A milk, which will be processed as grade A
- 8 milk or a grade A dairy product, as required under s. ATCP 60.17 65.38.
- 9 SECTION 11. ATCP 82.08 (3) (b) is amended to read:
- ATCP 82.08 (3) (b) Sanitize dairy product contact surfaces according to s. ATCP 80.18
- 11 65.34.
- 12 **SECTION 12.** ATCP 82.10 (1) (a) is amended to read:
- ATCP 82.10 (1) (a) If milk from a grade A or grade B dairy farm violates a standard under s.
- 14 ATCP 60.15 65.70 on any single test, milk from that farm shall be collected at least one every 2
- days until a subsequent test shows that the milk from that dairy farm complies with that standard.
- 16 This paragraph does not require a bulk milk weigher and sampler to collect milk if collection
- would violate ch, ATCP 60 65.
- 18 **SECTION 13.** ATCP 82.10 (6) (a) is amended to read:
- 19 ATCP 82.10 (6) (a) Before a bulk milk weigher and sampler collects milk at a dairy farm, the
- bulk milk weigher and sampler shall record the temperature of the milk to be collected, as shown
- on the dairy farm bulk tank indicating thermometer. If the milk is collected more than 2 hours
- 22 after the last milking, the bulk milk weigher and sampler shall reject the milk if the milk
- 23 temperature exceeds 45° F. (7° C.). If milk from 2 or more milkings is collected within 2 hours

- of the last milking, the bulk milk weigher and sampler shall reject the milk if the milk
- temperature exceeds 50° F. (10° C.). Milk which does not meet these temperature requirements
- may be collected if, within 4 hours after collection, the milk has begun to be processed
- 4 exclusively into milk or dairy products not designated as a grade A dairy product under s. ATCP
- 5 80.01 (14) 65.01 (26) and (15) (27).
- 6 SECTION 14. ATCP 82.12 (2m) (intro.) and (a) are amended to read:
- ATCP 82.12 (2m) (intro.) An individual shall comply with the following procedures when
- 8 collecting a milk sample from a bulk milk tanker under sub. (1) (c), unless the department
- 9 specifies a different procedure in its authorization under s. ATCP 60.11 (4) 65.16 (5).
- ATCP 82.12 (2m) (a) The individual shall collect the sample at the dairy plant where the
- bulk milk shipment is first received, in a receiving facility that complies with s. ATCP 80.20
- 12 (6)65.36 (6).
- 13 **SECTION 15.** ATCP 82.12 (4) (c) is amended to read:
- 14 ATCP 82.12 (4) (c) Large enough to hold milk for initial and repeat testing under s. ATCP
- 15 80.26 65.76, and large enough to permit thorough mixing of sample contents before testing.
- 16 **SECTION 16.** ATCP 100.98 (2) (a) and (b) are amended to read:
- 17 ATCP (2) (a) Dairy farm field service costs other than field service costs which are directly
- attributable to violations of ch. ATCP 60 65.
- 19 ATCP (2) (b) Costs to test dairy farm milk shipments before the dairy plant operator
- 20 commingles those milk shipments with other milk shipments at the dairy plant. Testing costs
- include lab testing, reporting and recordkeeping costs related to milk testing. Testing costs do not
- include costs incurred by a milk hauler to collect milk samples from dairy farms, nor do they
- 23 include costs incurred because of producer's violation of ch. ATCP 60 65.

1	SECTION 17. ATCP 100.982 (3) is amended to read:
2	ATCP 100.982 (3) Properly charging a producer, pursuant to ch. ATCP 60 65 or the
3	procurement contract, for costs which the dairy plant operator or milk contractor incurs because
4	of the producer's violation of ch. ATCP 60 65.
5	SECTION 18. ATCP 100.982 (4) (f) is amended to read:
6	ATCP 100.982 (4) (f) The dairy plant operator complies with ss. ATCP 80.26 (2) 65.84 (3)
7	and 100.30.
8	SECTION 19. EFFECTIVE DATE: This rule shall take effect on the first day of the month
9	following publication in the Wisconsin administrative register, as provided under s. 227.22 (2)
10	(intro).
	Dated thisday of, 2016.
	WISCONSIN DEPARTMENT OF AGRICULTURE,
	TRADE AND CONSUMER PROTECTION
	By
	Ben Brancel, Secretary
	Den Brancei, Secretary

Wisconsin Department of Agriculture, Trade and Consumer Protection

Final Regulatory Flexibility Analysis

Rule Subject: Milk and Milk Products

Adm. Code Reference: ATCP 65
Rules Clearinghouse #: 14-073

DATCP Docket #: 13-R-06 and 13-R-13

Rule Summary

The Department proposes a comprehensive revision to food safety rules chs. ATCP 60 (Dairy Farms) and ATCP 80 (Dairy Plants.) The objectives of this proposed rule are to 1) modernize current dairy farm and dairy plant inspection rules to ensure compliance with the federal Food and Drug Administration's (FDA) Pasteurized Milk Ordinance (PMO), 2) accommodate advances in dairying and manufacturing dairy products, 3) indicate which provisions of new federal regulations implementing the FDA Food Safety Modernization Act (FSMA) must be followed by dairy plant operators, and 4) continue ensuring the safety and quality of Wisconsin milk and milk products.

Consolidation of dairy farm and dairy plant rules into one rule

This rule revision consolidates chs. ATCP 60 and 80 into a newly created ch. ATCP 65 (Milk and Milk Products) in recognition of the growing integration between Wisconsin dairy farms and dairy plants, where dairy plants are sometimes located directly on a dairy farm. The consolidated rule eliminates duplication between the two previous rule chapters and creates a more user-friendly "one-stop" rule for the dairy industry.

Details of the revision

Wording was changed throughout to provide greater clarity and modernize terms. For example, references to "milk haulers" were changed to "bulk milk weigher and samplers" to reflect the actual name of the license held by people who collect, sample, and transport milk. References to "inspectors" were changed to "division representatives" to reflect the broader range of staff, e.g. sanitarians, food scientists, regulatory specialists, who may conduct inspections. Subchapter, section, and subsection chapter titles were also revised and re-ordered where necessary to more clearly reflect the content of the rule and provide a logical sequence. The following is a summary of other notable changes made to the rule. A complete list of changes may be found as part of the plain language analysis in the hearing draft.

ATCP 65.01, Definitions.

In revising the rule, the Department:

- Added definitions for "abnormal milk," "aseptic processing and packaging system,"
 "bulk tank unit," "facility," "grade A producer permit," and "qualified facility."
- Repealed and replaced definitions for "C-I-P equipment," "C-I-P milking equipment," and "C-I-P milk pipelines" with a definition of "C-I-P" which was numbered as 65.01 (9).
- Updated the definition for "dairy product" to be consistent with current statute.
- Replaced the term for "food safety division" with "division."
- Expanded the definition for "grade B milk" to clarify that grade B milk is not processed into fluid milk for consumption; it is only used in the production of nongrade "A" dairy products.
- Broadened the definition for "equipment" to cover equipment used on dairy farms and in dairy plants.
- Repealed the definition from ATCP 65.01 (6) for "dairy plant" and replaced it with the definition from ATCP 80.01 (5) for "dairy plant."
- Revised the definition of "milk" to be consistent with the PMO definition by including the phrases "practically free of colostrum, obtained by the complete milking of one or more healthy milking animals."
- Expanded the definition "procure milk" to indicate that procured milk must be acquired directly from a licensed milk producer.
- Clarified that "sanitizers" shall be in compliance with 21 CFR part 178.1010 or otherwise approved by the division.
- Repealed the definitions "single-service utensil" and "single-service package" and replaced them with a definition for the term "single-service articles."

ATCP 65.02, Milk producer license and permits; and fees.

ATCP 65.02 includes revised provisions that require a license for each milk producer, for each species of milk animal milked by a single milk producer, and each dairy farm operated by a milk producer at which milk is produced to be offered for sale. Previously, not all of these parameters were mentioned. The rule was also revised to clarify that a representative of the dairy plant may submit an application on behalf of a milk producer and that the dairy plant representative shall certify that both the dairy farm and milking operations comply with applicable requirements under the law. The rule now indicates that a licensed milk contractor (or the contractor's representative), who procures milk but does not operate a dairy plant, may submit the milk producer license application and certify compliance. The rule allows no more than one milk producer to have a Grade "A"

permit at a single dairy farm unless all of the milk shipped from that dairy farm is assigned to one bulk tank unit and each milk producer is licensed. The rule also describes conditions under which more than one Grade "A" milk producer permit may be held on one dairy farm. Finally, the rule adds the due date of April 30 for paying the annual license fee and indicates that milk producer license fees are non-refundable.

ATCP 65.04, Dairy plant licenses and permits; fees.

The rule clarifies that no dairy plant license is required for a farm manufacturing dairy products solely for the owner/operator, members of the farm household, or nonpaying farm guests or employees. It exempts licensed restaurants from a dairy plant license if they prepare or process commercially pasteurized dairy products. However, licensed restaurants are not allowed to package Grade "A" dairy products without holding a dairy plant license. The rule exempts retail food establishments licensed under s. 97.30, Stats., from the requirement to hold a dairy plant license if they process non-Grade "A" dairy products made from commercially pasteurized and packaged dairy products solely for retail sale. The rule does not modify dairy plant fees. It indicates that dairy plant license fees are non-refundable.

ATCP 65.08, Milkhouse.

ATCP 65.08 (2) prohibits locating milkhouse access driveways and doors such that animal waste could be tracked into the milkhouse.

ATCP 65.10, Dairy farm water supply.

ATCP 65.10 (3) was updated to require wells to comply with ch. NR 810 (Requirements for the Operation and Maintenance of Public Water Systems), in addition to chs. NR 811 (Requirements for the Operation and Design of Community Water Systems) and NR 812 (Well Construction and Pump Installation.) ATCP 65.10 (5) (a) clarifies that if a milk producer has more than one well, water from each well shall be tested at least once every two years. This change brings the provision into conformance with the PMO.

ATCP 65.14, Milking and milk handling systems.

ATCP 65.14 (5) recognizes the increasing adoption of modernized milking systems by incorporating PMO requirements for automatic milking installations, or robotic milking systems.

ATCP 65.22, Farm premises.

ATCP 65.22 (5) (c) prohibits mixing or storage of human waste or septage with animal manure. This provision was added to prevent recurrence of observed situations in which transmission of human fecal pathogens via dairy farm facilities was clearly possible.

ATCP 65.23, Federal requirements.

ATCP 65.23 indicates which requirements of the FDA Preventive Controls – Human Food rule implementing FSMA must be met by Wisconsin-licensed dairy plants.

ATCP 65.24, Construction and maintenance.

ATCP 65.24 (1) (b) states that a written variance from a construction standard may only be issued for dairy plants that do not hold a Grade A permit, i.e., Grade "B" plants. The PMO does not allow construction variances for Grade "A" dairy plants. ATCP 65.24 (1) (c) also prohibits dairy plants from being directly connected to a milking barn, milking parlor or animal housing area. This latter provision is intended to minimize transmission of pathogenic microorganisms into the dairy plant.

ATCP 65.24 (4) (a) revises a current exemption of overhead doors and electronic sliding doors in delivery areas from the requirement to be kept closed when not in use. The revised requirement excludes Grade "A" dairy plants from the exemption, while continuing to allow receiving stations and Grade "B" dairy plants to keep overhead and electronic sliding doors open when not in use. This change brings Wisconsin's regulations in compliance with the PMO.

ATCP 65.24 (8), Dairy plant water supply.

ATCP 65.24 (8) contains a modified requirement that water used in dairy products must comply with ch. NR 810 (Requirements for the Operation and Maintenance of Public Systems), in addition to chs. NR 811 (Requirements for the Operation and Design of Community Water Systems) and NR 812 (Well Construction and Pump Installation.)

ATCP 65.24 (8) (b) requires that water from a privately owned water system supplying a dairy plant shall be tested to ensure it meets safe drinking requirements under ch. NR 809 (Safe Drinking Water), after a repair or alteration. Finally, ATCP 65.24 (8) (h) was created to require Grade "A" dairy plants using water to flush pasteurized milk or milk products from their milk processing systems to use water that is of equivalent microbiological quality to pasteurized milk.

ATCP 65.28, Equipment and utensils.

ATCP 65.28 (7) (e) 5. was created to exempt dairy plants from having to clean certain reverse osmosis equipment after each day's use. ATCP 65.28 (7) (f) contains a modified requirement for a dairy plant operator to consult with FDA before seeking division approval of a proposal for alternative cleaning and sanitizing schedule for continuously-operated equipment that comes in contact with Grade "A" products. This provision now conforms with the PMO.

ATCP 65.36, Receiving milk and dairy products.

ATCP 65.36 (3) indicates that a bulk milk tanker transporting Grade "A" milk may hold a Grade "A" permit issued by another state's regulatory agency. This change recognizes reciprocity requirements of the PMO and recent changes in ch. ATCP 82 (Bulk Milk Collection, Sampling, and Transportation.)

ATCP 65.40, Storing and handling milk and dairy products.

ATCP 65.40 (2) allows the division to authorize alternative temperature limits for storing milk and milk products.

ATCP 65.40 (2) (d) 7. exempts acid whey with at least a minimum specified percent titratable acidity or no more than a maximum specified pH from storage time and storage temperature requirements applicable to other dairy products. This change is in response to information presented by industry.

ATCP 65.41, Low-acid or acidified dairy products packaged in hermetically sealed containers for non-refrigerated storage.

ATCP 65.41 (1) requires manufacturing of low-acid dairy products packaged in hermetically sealed containers for non-refrigerated storage to be done in compliance with federal canning regulations.

ATCP 65.41 (2) requires manufacturing of acidified dairy products packaged in hermetically sealed containers for non-refrigerated storage to be done in compliance with federal regulations pertaining to acidified canned foods.

ATCP 65.42, Recall plan.

ATCP 65.42 requires dairy plants manufacturing or processing dairy products to have a written plan for identifying and recalling dairy products should a food recall become necessary, and describes the required contents of such a plan. This new requirement is consistent with the recall plan requirements in ch. ATCP 70 (Food Processing Plants) and ch. ATCP 88 (Eggs). The new requirement does not apply to receiving stations or transfer stations.

ATCP 65.58, Pasteurization time and temperature.

ATCP 65.58 (1) requires that alternative methods of pasteurization of Grade "A" products be recognized by the FDA.

ATCP 65.72, Drug residue testing.

ATCP 65.72 (3) (c) was revised to indicate that a bulk load of milk must be agitated sufficiently to ensure that the sample taken for drug residue testing is representative of the bulk load of milk. Further revision allowed for Department approval of an alternative sampling methods that is not dependent on agitation to obtain a representative sample.

ATCP 65.72 (6) allows dairy plants to recover the cost of an entire bulk load of milk from a milk producer responsible for contaminating that load with milk adulterated with drug residues, or from the milk contractor from whom the milk was procured. The milk contractor may, in turn, recover the cost of the entire load from the milk producer responsible for contaminating that load with milk adulterated with drug residues.

ATCP 65.74, Milk and dairy products; quality standards.

ATCP 65.74 (2) (a) states that bacterial counts for nonfat dry milk shall not exceed 10,000 per gram. This provision is in conformance with the PMO.

ATCP 65.910, Inspection of dairy farms; general.

ATCP 65.910 (2) increases the inspection frequency for Grade "B" dairy farms from once every two years to once a year. This provision is made to ensure maintenance of adequate conditions on the Grade "B" dairy farms.

ATCP 65.912, Performance-based farm inspection.

ATCP 65.912 contains language which was modified to bring Wisconsin's performance-based farm inspection program in full compliance with Appendix P of the PMO. Specifically, the rule prohibits placing farms in categories requiring inspection once or twice per year under the program if they have been cited during the past year with any violation that presents an imminent health hazard. The rule also prohibits placing farms in a category requiring inspection once or twice per year if they have received a warning under s. ATCP 65.923 (1) during the past year. ATCP 65.923 (1) continues to require the division to issue a warning notice if an inspection finds a noncompliance with a key violation. However, the definition of a key violation was expanded to include instances when a farm receives one or more identical violations during two consecutive inspections, i.e., double debits. Finally, the rule prohibits placing farms in categories requiring inspection once or twice per year if the milk shipped from the farm was found to have had any drug residues during the past year.

ATCP 65.923, Drug residue violations; milk producer sanctions.

ATCP 65.923 requires the Department to issue a warning notice whenever a producer milk sample test result is confirmed positive for drug residue. Once a milk producer receives a warning notice for drug residues, the milk producer must implement a drug residue prevention program within 21 days of the effective date of the notice or the producer's Grade A permit will be suspended. If the drug residue prevention program isn't completed within 45 days, the milk producer's license will be suspended. The rule already included this requirement, along with a penalty provision to be invoked if the producer has 3 drug residue violations within 12 months. These penalties are modified in the proposed rule and a penalty is created in sub. ATCP 65.922 (4) for milk producers whose milk sample yields a confirmed positive test result for drug residue in a second

separate 24-hour period within 12 months of the first violation After the second offense, the proposed rule requires the license to be suspended for 5 days unless the milk producer agrees within 15 days of the warning notice taking effect to pay a civil forfeiture or to discard one milk shipment; the milk producer must also complete participation in a drug residue prevention program and present a certificate of completion for the program within 180 days of receiving a warning letter. Milk producers whose milk sample yields a confirmed positive test result for drug residues in a third separate 24-hour period within 12 months of the first violation would have their milk producer license suspended for 10 days unless the milk producer agrees within 15 days of the warning notice taking effect to pay two civil forfeitures or to discard two milk shipments; the milk producer would also have to develop and implement a Department-approved drug residue program and present documentation indicating that this program has been implemented for at least 90 days.

ATCP 65.928, Right of hearing.

ATCP 65.928 (3) contains a revised requirement the Department hold an informal hearing within 20 days, rather than 10 days, of receiving a hearing request. This change will bring the rule into compliance with ch. ATCP 1 (Administrative Orders and Contested Cases).

ATCP 65.928 (4) is revised to eliminate the 10 day requirement for requesting a contested case hearing, in conformance with Subch. III, ch. 227, Stats., and s. ATCP 1.03 (3) (a) 1. It is also revised to add that a request for a contested case hearing must follow the requirements in s. ATCP 1.06.

Small Businesses Affected

The proposed rule changes will impact dairy producers and dairy plants, many of which may be small businesses. The proposed rule does not substantially alter the vast majority of the requirements dairy-related businesses already meet. The rule does not increase license or permit fees. All Grade "A" dairy businesses, whether large or small, must meet regulations that are substantially in compliance with the FDA's PMO in order to collect, sample, and transport Grade "A" dairy products and no special accommodation may be made for small businesses. The proposed rule does not make accommodations for small Grade "B" dairy businesses. The proposed rule allows Grade "B" businesses to seek variances from some requirements and incorporates more flexibility than for Grade "A" businesses. However, to protect food safety and the quality of Wisconsin milk and milk products, further flexibility based on business size is not possible. The rule proposes an increase in the frequency of inspection for Grade "B" dairy farms to more effectively ensure that these farms remain in compliance.

If the proposed rule is adopted, some dairy producers may incur costs if they need to modify access to the milkhouse to avoid contamination with animal waste. A few milk producers may also be required to participate in a drug residue prevention program if they have milk samples test positive twice within 12 months. Some farms may need to have load-out doors installed to meet requirements for the location of bulk transport containers

that receive milk directly from the milking equipment ("direct ship" milking). Some onfarm dairy plants will have to construct an intervening room with two doors to minimize the likelihood of contaminants being tracked from the milking barn, milking parlor, or animal husbandry areas to the dairy plant. In general, the rule changes are expected to impact only a small number of dairy farms and dairy plants.

Some of the rule changes may result in cost savings or provide other benefits to industry. For example, the rule contains certain exemptions from dairy plant licensing for permitted restaurants and licensed retail food establishments. The rule also allows the Division of Food Safety (DFS) to authorize alternative temperature limits for storing non-Grade "A" milk or milk products. It exempts acid whey with specified percent titratable acidity or pH from storage time and storage temperature requirements applicable to other dairy products. It also exempts Grade "B" whey (not meeting the above requirements for acid whey) in specified situations from the storage time and temperature requirements. These changes are in response to information presented by industry.

Reporting, Bookkeeping and other Procedures

The proposed rule would not require any additional reporting or bookkeeping, but would require dairy plant operators to prepare a written recall plan.

Professional Skills Required

The proposed rule does not require any new professional skills by small businesses.

Accommodation for Small Business

All Grade "A" dairy farms and dairy plants, whether large or small, must meet regulations that are substantially in compliance with the Food and Drug Administration's Pasteurized Milk Ordinance. No special accommodation for Grade "A" small dairy businesses may be made. Grade "B" dairy farms and dairy plants have more flexibility than Grade "A" dairy businesses, but Grade "B" dairy businesses also must meet certain requirements in order to produce safe, high-quality milk and milk products.

Conclusion

The provisions in this proposed rule will benefit Wisconsin's dairy industry and are expected to impose minor costs for only a few dairy farms and dairy plants.

This rule will not have a significant adverse effect on "small business" and is not subject to the delayed "small business" effective date provided in s. 227.22(2)(e), Stats.

The Department will, to the maximum extent feasible, seek voluntary compliance with this rule.

Dated this 16th day of March, 2016.

STATE OF WISCONSIN DEPARTMENT OF AGRICULTURE, TRADE AND CONSUMER PROTECTION

Steven C. Ingham, Administrator,

Division of Food Safety

STATE OF WISCONSIN DEPARTMENT OF ADMINISTRATION DOA 2049 (R 07/2011)

ADMINISTRATIVE DILES

FISCAL ESTIMATE AND ECONOMIC IMPACT ANALYSIS					
Type of Estimate and Analysis					
☐ Original ☐ Updated ☐ Corrected Administrative Rule Chapter, Title and Number					
Administrative Rule Chapter,	Title and Number				
ATCP 65, Milk and Mil	k Products. This rule replace	es ATCF	60, Dairy Farms, and ATCP 80, Dairy Plants.		
Subject	N. C.				
Dairy farms, dairy plan	nts, milk and milk product	t regulat	ions, and affecting small business.		
Fund Sources Affected		· · · · · · · · · · · · · · · · · · ·	Chapter 20 , Stats. Appropriations Affected		
	O PRS SEG SEG-S		20.115 (1)(a) 20.115 (1) (gb)		
Fiscal Effect of Implementing	the Rule				
☐ No Fiscal Effect	☐ Increase Existing Revenue	s	☐ Increase Costs		
Indeterminate	Decrease Existing Revenue		☑ Could Absorb Within Agency's Budget		
			Decrease Costs		
The Rule Will Impact the Fol	lowing (Check All That Apply)				
State's Economy			ific Businesses/Sectors		
Local Government Uni			ic Utility Rate Payers		
Would Implementation and C	Compliance Costs Be Greater Than	\$20 millio	n?		
☐ Yes ⊠ No					
Policy Problem Address		v 1.2. ing			
The Department proposes a comprehensive revision to food safety rules ATCP 60 (Dairy Farms) and ATCP 80 (Dairy Plants.) The objective of this proposed rule is to modernize current dairy farm and dairy plant inspection rules to ensure compliance with the federal Food and Drug Administration's (FDA) Pasteurized Milk Ordinance (PMO), accommodate advances in dairying and manufacturing dairy products, indicate which provisions of new federal regulations implementing the FDA Food Safety Modernization Act (FSMA) must be followed by dairy plant operators, and continue ensuring the safety and quality of Wisconsin milk and milk products. FDA revises the PMO every two years and the Department must periodically revise its dairy farm and dairy plant rules to incorporate changes in the PMO, ensuring compliance with the PMO. States must meet PMO requirements in order for their Grade "A" milk and milk products to be shipped in interstate commerce. The consolidation of ATCP 60 and ATCP 80 into ATCP 65 (Milk and Milk Products) recognizes the growing integration between Wisconsin dairy farms and dairy plants, where dairy plants are sometimes located directly on a dairy farm. The revised rule eliminates duplication between the two previous rule chapters and creates a more user-friendly "one-stop" rule for the dairy industry. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local					
Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)					

Businesses and Business Sectors

The proposed rule changes will impact dairy producers and dairy plants, many of which may be small businesses. The proposed rule does not substantially alter the vast majority of requirements dairy-related businesses already meet. The rule does not increase license or permit fees. All Grade "A" dairy businesses, whether large or small, must meet regulations that are substantially in compliance with the FDA's PMO in order to collect, sample, and transport Grade "A" dairy products and no special accommodation may be made for small businesses. The proposed rule does not make accommodations for small Grade "B" dairy businesses. The proposed rule allows Grade "B" businesses to seek variances from some requirements and incorporates more flexibility than for Grade "A" businesses. However, to protect food safety and the quality of Wisconsin milk and milk products, further flexibility based on business size is not possible. The rule proposes an increase in the frequency of inspection for Grade "B" dairy farms to more effectively ensure that farms remain in compliance.

If the proposed rule is adopted, some dairy producers may incur costs if they need to modify access to the milkhouse to avoid contamination with animal waste. A few milk producers may also be required to participate in a drug residue prevention program if they have milk samples test positive twice within 12 months. Some farms may need to have load-out doors installed to meet requirements for the location of bulk transport containers that receive milk directly from the milking equipment ("direct ship" milking). Some on-farm dairy plants will have to construct an intervening room with two doors to minimize the likelihood of contaminants being tracked from the milking barn, milking parlor, or animal husbandry areas to the dairy plant. In general, the rule changes are expected to impact only a small number of dairy farms and dairy plants.

Some of the rule changes may result in cost savings or provide other benefits to industry. For example, the rule contains certain exemptions from dairy plant licensing for permitted restaurants and licensed retail food establishments. The rule also allows the Division of Food Safety (DFS) to authorize alternative temperature limits for storing non-Grade "A" milk or milk products. It exempts acid whey with specified percent titratable acidity or pH from storage time and storage temperature requirements applicable to other dairy products. Apart from this exemption, it also exempts Grade "B" whey in specified situations from the storage time and temperature requirements. These changes are in response to information presented by industry.

The proposed rule also assists small businesses by consolidating dairy farm and dairy plant regulations into one rule.

State's Economy

The rule will benefit the state's economy by ensuring Wisconsin's dairy industry meets federal standards for Grade "A" milk and milk products. Wisconsin has over 10,000 licensed milk producers and ranked second nationally in milk production. Milk is shipped from each dairy farm to one of more than 400 licensed dairy plants in the state or to a licensed dairy plant in another state. About 98% of the milk produced in Wisconsin is Grade "A." Grade "A" unpasteurized milk, along with pasteurized milk and certain other dairy products made from Grade "A" milk can only be shipped across state and international boundaries if the production, transportation, processing, and regulatory oversight are in accordance with the PMO.

Local Governmental Units and Public Utility Rate Payers

The rule will have no impact on local governmental units or public utility rate payers.

Economic Impact Analysis Comments

The Department posted the proposed rule online as required under Wis. Stat. § 227.137 and solicited comments from organizations representing Wisconsin's dairy producers and dairy plants, including the Wisconsin Farm Bureau Federation, Wisconsin Farmers Union, Professional Dairy Producers of Wisconsin, Wisconsin Cheese Makers Association, the Cooperative Network, and the Wisconsin Dairy Products Association. The Department did not receive any comments on the economic impact of the rule.

Fiscal Impact

Since dairy farms and dairy plants are already regulated by the Department, this rule will not have a significant fiscal impact on state government and the Department will absorb any costs with current budget and staff. This rule will have no fiscal effect on local governments or public utility rate payers.

This rule continues to ensure that Wisconsin's dairy industry meets federal Pasteurized Milk Ordinance (PMO) requirements. Not implementing the rule could jeopardize Wisconsin dairy's world class reputation and Wisconsin could be prohibited from shipping Grade A milk and milk products in interstate commerce.

Long Range Implications of Implementing the Rule

There are no long range negative implications of implementing the rule. In the long run, the rule will continue to allow Wisconsin dairy farms and dairy plants to ship Grade A milk and milk products in interstate commerce.

Compare With Approaches Being Used by Federal Government

The proposed rule makes Wisconsin's dairy farm and dairy plant regulations more consistent with the PMO. Although compliance with the PMO is technically a voluntary effort by state regulatory agencies, Wisconsin is periodically evaluated by the FDA for compliance with the PMO. Failure to pass the FDA audit would jeopardize the state's interstate and international dairy industry. The rule changes will bring Wisconsin's dairy farm and dairy plant regulations into further compliance with the 2013 revision of the PMO.

Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

Michigan, Minnesota, Iowa, and Illinois adopt the PMO as part of their grade "A" dairy-related statutes and regulations and therefore enforce Grade "A" dairy regulations similar to those enforced by Wisconsin. Unlike Wisconsin, none of the surrounding states have adopted performance-based farm inspection, as allowed by the PMO.

Name and Phone Number of Contact Person

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